

Exhibit 300: Capital Asset Plan and Business Case Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview

1. **Date of Submission:** 2011-02-28
2. **Agency:** 009
3. **Bureau:** 10
4. **Name of this Investment:** FDA Mission Accomplishments and Regulatory Compliance Services
5. **Unique Project (Investment) Identifier (UPI):** 009-10-01-03-01-8021-00
6. **What kind of investment will this be in FY 2012?:** Mixed Life Cycle
 - Planning
 - Full Acquisition
 - Operations and Maintenance
 - Mixed Life Cycle
 - Multi-Agency Collaboration
7. **What was the first budget year this investment was submitted to OMB?** FY2004

8.

- a. **Provide a brief summary of the investment and justification, including a brief description of how this closes in part or in whole an identified agency performance gap, specific accomplishments expected by the budget year and the related benefit to the mission, and the primary beneficiary(ies) of the investment.**

The MARCS program is the primary IT mechanism for realizing ORA program goals. It also directly supports the programs of CBER, CDER, CDRH, CFSAN, and CVM. MARCS manages the integration, reengineering and enhancement of seven legacy systems into work flows and services to better support these programs. It aligns directly with Objective 2.2 of the HHS strategic plan: Protect the Public Against Injuries and Environmental Threats and enables FDA Centers to meet FDA Strategic Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain. FDA uses MARCS' applications to: plan FDA field activities and assign staff to inspections, investigations, recalls and other compliance activities; track and control samples and the results of laboratory analysis; collect and maintain information from field activities; collect performance data, particularly that related to FDAAA; send Prior Notice for food imports to Customs and accept import product information from Customs for screening; screen some 20 million import lines a year based on calculated risk; collect information about the facilities FDA regulates and those in the import supply chain for risk-based targeting; provide FDA Centers with information on inspections, compliance actions, recalls, laboratory analysis and facilities. MARCS fills the current performance gap by providing for 1 the convergence of Center and ORA workflows, in particular for compliance, recalls, and complaints 2 the convergence of Imports and Domestics workflows by reengineering and integrating components 3 better cooperation through electronic communication with industry, academia, and state and local organizations through such components as eSAF, ITACS, and CLEARs 4 a national workforce where resources can be assigned using WAAM and ARMS to any area of the USA rather than being confined to only one geographical area. 5 reusable services for MARCS and other FDA investments to reduce duplication of effort This is being accomplished by improving upon and replacing legacy functionality according to useful segments. Services such as ARMS, NS and DGS and work flows such as ITACS, Inspections and Field Exams are expected to be fully implemented by the budget year. Additional integration with other FDA investments such as ALM, RBIS, HI, and cEDR will enhance functionality. MARCS will also support functionality for tobacco regulation.

- b. **Provide any links to relevant websites that would be useful to gain additional information on the investment including links to GAO and IG reports.**

Title	Link
NONE	

9.

a. **Provide the date of the Agency's Executive/Investment Committee approval of this investment.**

2009-07-21

b. **Provide the date of the most recent or planned approved project charter.** 2010-01-29

10. **Contact information?**

a. **Program/Project Manager Name:** *

Phone Number: *

Email: *

b. **Business Function Owner Name (i.e. Executive Agent or Investment Owner):** Roosevelt, Michael

Phone Number: *

Email: *

11. What project management qualifications does the Project Manager have? (choose only one per FAC-P/PM or DAWIA): Project manager has been validated according to FAC-P/PM or DAWIA criteria as qualified for this investment.

- Project manager has been validated according to FAC-P/PM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/PM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.B.1: Summary of Funding
(In millions of dollars)

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total
Planning:	*	*	*	*	*	*	*	*	*
Acquisition:	*	*	*	*	*	*	*	*	*
Planning & Acquisition Government FTE Costs	*	*	*	*	*	*	*	*	*
Subtotal Planning & Acquisition(DME):	*	*	*	*	*	*	*	*	*
Operations & Maintenance:	*	*	*	*	*	*	*	*	*
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*
Operations, Maintenance, Disposition Government FTE Costs	*	*	*	*	*	*	*	*	*
Subtotal O&M and Disposition Costs (SS):	*	*	*	*	*	*	*	*	*
TOTAL FTE Costs	*	*	*	*	*	*	*	*	*
TOTAL (not including FTE costs):	*	*	*	*	*	*	*	*	*
TOTAL (including FTE costs):	*	*	*	*	*	*	*	*	*
Number of FTE represented by	*	*	*	*	*	*	*	*	*

Table I.B.1: Summary of Funding
(In millions of dollars)

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total
Costs:									

2. Insert the number of years covered in the column “PY-1 and earlier”: 6

3. Insert the number of years covered in the column “BY+4 and beyond”: *

4. If the summary of funding has changed from the FY 2011 President’s Budget request, briefly explain those changes:

*

Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Competed	Short description of acquisition
Awarded	7524	Various--Contracts completed in prior years		Not Available	*	*	\$7.7	Cost Plus Fixed Fee	N	2003-09-30	2005-09-30	Full and Open Competition	DME and SS work by various contracts including pilot, planning, requirements, design, early versions
Awarded	7524	HHSF223200550072W		Not Available	*	*	\$6.5	Cost Plus Fixed Fee	N	2005-04-08	2007-09-30	Full and Open Competition	DME and SS work on FACTS and eSAF
Awarded	7524	HHSF223200550067W		Not Available	*	*	\$8.6	Cost Plus Fixed Fee	N	2005-04-01	2007-09-30	Full and Open Competition	DME and SS work on OASIS and PNSI
Awarded	7524	HHSF223200550262G		Not Available	*	*	\$5.3	Time and Materials	N	2005-07-01	2010-06-30	Full and Open Competition	DME and SS work on RES
Awarded	7524	HHSF22320055003C		Not Available	*	*	\$2.0	Cost Plus	N	2005-09-03	2008-08-31	Full and	DME and SS

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Completed	Short description of acquisition
								Fixed Fee				Open Competition after exclusion of sources	work on MARCS Interface and Center Views
Awarded	7524	IAG 224-07-4004		Not Available	*	*	\$4.9	Labor Hours	N	2005-01-28	2010-06-30	Not Completed	DME and SS work on Turbo EIR, Turbo on the Web, IMF, and MARS
Awarded	7524	HHSF223200550297 G		Not Available	*	*	\$8.6	Time and Materials	N	2005-01-12	2008-05-09	Full and Open Competition	Subject Matter Expertise IT support
Awarded	7524	HHSF223200650508 W		Not Available	*	*	\$1.3	Cost Plus Fixed Fee	Y	2006-10-02	2008-08-31	Full and Open Competition	DME and SS work on SERS
Awarded	7524	HHSF223200750357W			*	*	\$21.2	Firm Fixed Price	N	2007-09-01	2009-09-20	Y	MARCS LEGACY SYSTEMS
Awarded	7524	DAAE30-99-D-1013		Not Available	*	*	\$1.9	Firm Fixed Price	N	2009-03-01	2010-03-31	Not Completed	Work to support PREDICT.

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Completed	Short description of acquisition
Awarded	7524	HHSF223200950003C		FDA09SOL2230900062	*	*	\$3.5	Labor Hours	Y	2009-06-23	2010-07-31	N	IT SUPPORT SERVICES
Awarded	7524	INN10PC18073		14060409RP21461	*	*	\$98.0	Firm Fixed Price	Y	2009-12-31	2014-11-23	Full and Open Competition	DME and SS work on MARCS. This is with one prime integrator.
Awarded	7524	HHSF223201000047L			*	*	\$4.2	Order Dependent (IDV only)	Y	2010-09-16		Y	OTHER ADP & TELECOMMUNICATIONS SVCS

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

*

3.

- a. Has an Acquisition Plan been developed? If yes, please answer the questions that follow *
- b. Does the Acquisition Plan reflect the requirements of FAR Subpart 7.1 *
- c. Was the Acquisition Plan approved in accordance with agency requirements *
- d. If "yes," enter the date of approval? *
- e. Is the acquisition plan consistent with your agency Strategic Sustainability Performance Plan? *
- f. Does the acquisition plan meet the requirements of EOs 13423 and 13514? *
- g. If an Acquisition Plan has not been developed, provide a brief explanation.

*

Part II: IT Capital Investments

Section A: General

1.
 - a. Confirm that the IT Program/Project manager has the following competencies: configuration management, data management, information management, information resources strategy and planning, information systems/network security, IT architecture, IT performance assessment, infrastructure design, systems integration, systems life cycle, technology awareness, and capital planning and investment control. yes
 - b. If not, confirm that the PM has a development plan to achieve competencies either by direct experience or education.
2. Describe the progress of evaluating cloud computing alternatives for service delivery to support this investment. cloud computing alternatives are being investigated by the office of information management.
3. Provide the date of the most recent or planned Quality Assurance Plan 2010-09-10
4.
 - a. Provide the UPI of all other investments that have a significant dependency on the successful implementation of this investment. 009-10-01-03-01-8033-00,009-10-01-03-01-8013-00
 - b. If this investment is significantly dependent on the successful implementation of another investment(s), please provide the UPI(s). 009-10-01-03-01-8033-00
5. An Alternatives Analysis must be conducted for all Major Investments with Planning and Acquisition (DME) activities and evaluate the costs and benefits of at least three alternatives and the status quo. The details of the analysis must be available to OMB upon request. Provide the date of the most recent or planned alternatives analysis for this investment. 2009-05-30
6. Risks must be actively managed throughout the lifecycle of the investment. The Risk Management Plan and risk register must be available to OMB upon request. Provide the date that the risk register was last updated. 2010-05-21

Section B: Cost and Schedule Performance

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
COMPLETED MARCS OPERATIONS DME: Baseline Systems Web Migration, Tactical Work Plan Pilot, Design/Development, Stand up test and operational environment to support 24/7; MARCS External Interface, User Access; MARCS Interface, Integration with portal	DME	*	\$16.3	\$16.3	2005-08-30	2005-08-30	2008-09-30	2008-09-30	100.00%	100.00%
COMPLETED MARCS SERVICES DME: Standardized Evidence Reference Services Planning & Acquisition; Standardized Evidence Reference Services Prototype; National Sample Distributor	DME	*	\$1.8	\$1.8	2005-06-30	2005-06-30	2008-03-21	2008-03-21	100.00%	100.00%
COMPLETED MARCS MANAGEMENT	DME	*	\$13.2	\$13.2	2004-06-01	2004-06-01	2008-09-30	2008-09-30	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
DME: Preliminary Planning, Requirements, Design, Feasibility, Database										
Import Operations 1: ITACS, Enhanced Entry Review, PREDICT Integration, PN Targeting, PNSI Final Rule, PNSI Enhance Usability, PNSI Log in and Startup, PNSI Batch Submissions, enhance to browse status messages, error messages, CBP files, SQL menu	DME	*	\$3.6	\$3.2	2008-10-01	2008-10-01	2010-09-30	2010-09-30	100.00%	100.00%
Import Operations 2: Move all of OASIS off of Oracle forms. Move PNSI off of Oracle Forms, additional enhancements	DME	*	\$2.4	\$0.9	2010-10-01	2010-10-01	2012-09-30		39.53%	37.44%
PREDICT: Move from Pilot into	DME	*	\$1.9	\$1.9	2009-09-01	2009-09-01	2010-09-30	2010-09-30	100.00%	100.00%

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Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Production. FY08 Supplemental Funds										
Domestic Operations 1: Seafood HACCP, retire compliance activity functionality once ALS is integrated, move parts of FACTS off of Oracle Forms, additional enhancements	DME	*	\$1.6	\$1.3	2008-10-01	2008-10-01	2010-09-30	2010-09-30	100.00%	100.00%
Domestic Operations 2: Move all of FACTS off of Oracle forms, FACTS support for WAAM CAR, additional enhancements	DME	*	\$2.0	\$0.4	2010-10-01	2010-10-01	2012-09-30		20.36%	15.40%
MARCS Operations 1: Requirements, Future enhancements	DME	*	*	*	2012-10-01	*	2014-09-30	*	*	*
Recalls Enterprise System (RES) 1: Support for Centers, CBER Direct Recall Classification, MARCS Frame, separate email notifications as a start for	DME	*	\$2.1	\$2.1	2005-06-30	2005-06-30	2009-06-30	2009-06-12	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Notification Services, medium and low center priorities										
Recalls Enterprise System (RES) 2: Integration with SERS, Firm Finder, and PREDICT. Improved audit checking, mandatory spell check, enforcement report, product code conversion, application streamlining, reporting support, medium and low priorities	DME	*	\$2.1	\$1.3	2009-07-01	2009-08-03	2011-06-30		63.86%	61.77%
Recalls Enterprise System (RES) 3: Requirements, future enhancements (possibly Pre-Market, additional Center needs, international recalls)	DME	*	\$1.5	\$0.0	2011-07-01		2013-06-30		0.00%	0.00%
Field Work Manager (FWM) 1: Core, IMC, Field Exams	DME	*	\$1.5	\$1.4	2008-04-01	2008-04-01	2009-09-30	2009-09-30	100.00%	100.00%
Field Work Manager (FWM)	DME	*	\$2.4	\$2.8	2009-10-01	2009-10-01	2011-09-30		83.41%	83.03%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
2: Field Exams, Sample Collection, Recalls, Complaints, Investigations, Inspections, Compliance										
Field Work Manager (FWM)	DME	*	\$1.6	\$0.0	2011-10-01		2013-09-30		0.00%	0.00%
3: Recalls, Complaints, Investigations, Inspections, Compliance										
Center Views 2: Single Sign On, enhanced search capability, display for information from CDER and CFSA systems, CBER and CDRH tab enhancements	DME	*	\$0.4	\$0.9	2009-08-01	2009-09-21	2010-09-30		100.00%	99.00%
Compliance Management System	DME	*	\$1.0	\$0.1	2009-10-01	2009-12-31	2011-09-30		10.40%	10.40%
Contract Laboratory Evaluation and Review System (CLEARs): Requirements, Contract Laboratory Accreditation Registry and Tracking, Advance Notice Intent to use	DME	*	\$3.0	\$0.5	2009-08-01	2009-12-31	2011-09-30		16.36%	16.86%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Accredited Laboratory, Submission and Review of Abbreviated and Full Laboratory Packages										
Activity Log Service (ALS) 1: Triggers in Domestic to ALS, modify Domestics to view activities	DME	*	\$1.7	\$1.6	2006-06-01	2006-06-01	2009-08-31	2009-08-31	100.00%	100.00%
Activity Log Service (ALS) 2: UI for searching, creating, modifying, and annotating activities	DME	*	\$0.9	\$0.0	2009-10-01		2010-06-30		100.00%	0.00%
Activity Log Service (ALS) 3: Reporting support, administration module UI	DME	*	\$0.8	\$0.0	2010-07-01		2011-03-31		100.00%	0.00%
Notification Services: Email notifications	DME	*	\$0.5	\$1.0	2009-09-01	2009-12-31	2010-09-30		100.00%	98.00%
Work Assignment and Accomplishment Manager (WAAM) 1: Requirements, Tactical Work Planner, Work Assignment Manager, Time Reporter,	DME	*	\$3.5	\$1.4	2009-12-01	2009-12-31	2011-10-31		34.62%	30.52%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Compliance Achievement Reporter (CAR), Accomplishment Reporting, National Work Distributor										
Work Assignment and Accomplishment Manager (WAAM) 2: Requirements, Tactical Work Planner, Compliance Achievement Reporter (CAR), Accomplishment Reporting, National Work Distributor	DME	*	\$3.4	\$0.0	2011-08-01		2013-07-31		0.00%	0.00%
Data Sharing Service (DSS) 1: Support for PREDICT, support for Center Views, marketing status data, locator functionality. Includes 1.500 FY08 Supplemental Funds	DME	*	\$2.0	\$0.1	2009-07-01	2009-08-01	2010-09-30		100.00%	7.27%
Data Sharing Service (DSS) 2: Requirements, Access to ORA databases	DME	*	\$1.8	\$0.0	2010-07-01	2010-10-01	2012-06-30		5.34%	2.31%
Standardized	DME	*	\$0.2	\$0.3	2008-09-01	2008-09-01	2009-08-31	2009-08-31	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Evidence Reference Services (SERS) 2: Link electronic documents, user interface										
Standardized Evidence Reference Services (SERS) 3: Requirements, complete user interface, metadata redesign, future enhancements	DME	*	\$1.0	\$1.6	2009-09-01	2009-09-01	2011-09-30		99.00%	98.70%
Business Document Creator Service (BDCS): Requirements, set of document templates, code to access and produce documents for compliance, investigations, inspections, etc.	DME	*	\$1.2	\$0.4	2010-06-01	2010-09-27	2013-03-31		30.03%	34.02%
Data Look Up and Code Management Service (DLCMS): Requirements, capability for designated users to change, add, and delete codes (such as PAC codes) used in	DME	*	\$1.3	\$0.0	2010-10-01		2012-09-30		1.38%	0.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
lookup tables and selections										
User Workspace Management (UWM): Requirements, allows users to store filter, search, and display options for all applications	DME	*	\$0.4	\$0.0	2011-10-01		2012-09-30		0.00%	0.00%
Integration Within MARCS 1: Feasibility of migrating character-based and other applications, investigate design alternatives, Imports IMF integration, SERS and Turbo integration. OASIS FACTS Field Exam Integration, Accomplishment Hours, User Roles	DME	*	\$3.3	\$6.6	2008-10-01	2008-10-01	2010-09-30	2010-09-30	100.00%	100.00%
Integration Within MARCS 2: Imports and Domestics integration with ALS to access administration module. Integration	DME	*	\$4.5	\$3.5	2010-10-01	2010-10-01	2012-09-30		70.90%	68.19%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
between services and Imports, Domestics, RES, FWM, WAAM. Integration between WAAM and Imports, Domestics, RES, FWM										
Integration Within MARCS 3: Continued integration with services and between components, SERS and DSS integration	DME	*	*	*	2012-10-01	*	2014-09-30	*	*	*
Integration with Other FDA Investments 1: MARCS Firm Management Service Integration, FACTS and CMS Integration, SERS integration, Imports and Domestics integration with RBIS. Integration with FURLS (HI) (PNSI, eSAF, ITACS), ALM (QMIS), RBIS, PQC	DME	*	\$1.5	\$2.1	2008-10-01	2008-10-01	2010-09-30	2010-09-30	100.00%	100.00%
Integration with Other FDA Investments 2: Integration with	DME	*	\$2.8	\$1.0	2010-10-01	2010-10-01	2012-09-30		37.34%	27.50%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
ALM, RBIS, CMS, EON, HI for product information, PQC, FASTAR for services, cEDR										
Integration with Other FDA Investments 3: Integration with ALM, RBIS, EON, HI for product information, PQC, FASTAR for services	DME	*	*	*	2012-10-01	*	2014-09-30	*	*	*
Integration Outside FDA 1: State Systems Automated Interface to eSAF, eSAF Non-contracted State Inspections, eSAF State Data Transfer, eSAF Support for Additional Programs, ITDS/ACE, USDA, DHS, CDC	DME	*	\$0.6	\$0.6	2008-10-01	2008-10-01	2010-09-30	2009-09-30	100.00%	100.00%
Integration Outside FDA 2: RES 2 integration with the States, VA, USDA, other Federal Agencies, other national governments.	DME	*	\$0.8	\$0.5	2010-10-01	2010-10-01	2012-09-30		56.97%	48.02%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
MARCS integration with the States, VA, USDA, DHS, CDC, other Federal Agencies, other national governments										
Integration Outside FDA 3: MARCS integration with the States, VA, USDA, DHS, CDC, other Federal Agencies, other national governments	DME	*	*	*	2012-10-01	*	2014-09-30	*	*	*
Management Reserve: Funds in reserve to deal with Congressional mandates or emergencies that can not be determined in advance such as a greater focus on imports, domestics, recalls, compliance and prosecution, international cooperation, etc.	DME	*	\$2.7	\$0.0	2009-10-01		2013-09-30		1.89%	0.00%
Security: Authorization, Roles, and	DME	*	\$7.1	\$1.8	2008-10-01	2008-10-01	2013-09-30		28.64%	23.80%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Responsibilities Management Service, FDA FTEs, contractors, POA&M, C&A.										
EA CPIC: FDA FTEs, contractors, CPIC, E-300, EA.	DME	*	\$3.4	\$0.8	2008-10-01	2008-10-01	2013-09-30		28.86%	24.24%
Program Management: FDA FTEs, contractors, program management, project management, EPLC, scheduling, tracking, and planning.	DME	*	\$9.9	\$5.8	2008-10-01	2008-10-01	2013-09-30		60.09%	59.67%
Long term Enhancements to address Regulatory Changes and FDA Environment Change	DME	*	*	*	2013-10-01	*	2019-09-30	*	*	*
COMPLETED MARCS SS: SS Operations FY06-, SS Operations FY07, SS Operations FY08	SS	*	\$10.4	\$10.4	2005-10-01	2005-10-01	2008-09-30	2008-09-30	100.00%	100.00%
VMS to Unix Migration Phase 1 (Production DB)	SS	*	\$1.2	\$1.2	2006-03-31	2006-03-31	2008-08-15	2008-08-15	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
SS Operations FY09	SS	*	\$3.9	\$3.7	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%
VMS to Unix Migration Phase 2 (Back End DB)	SS	*	\$0.8	\$0.8	2008-01-10	2008-01-10	2009-06-30	2009-06-19	100.00%	100.00%
SS PREDICT FY09: Expansion of Risk Rules, Training. FY08 Supplemental Funds	SS	*	\$0.7	\$0.7	2008-10-01	2008-10-01	2009-09-30	2009-10-09	100.00%	100.00%
SS Operations FY10	SS	*	\$8.0	\$7.7	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
SS Operations FY11	SS	*	\$9.1	\$4.0	2010-10-01	2010-10-01	2011-09-30		50.00%	49.71%
SS Operations FY12	SS	*	\$8.9	\$0.0	2011-10-01		2012-09-30		0.00%	0.00%
SS Operations FY13	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*
SS Operations FY14 - FY19	SS	*	*	*	2013-10-01	*	2019-09-30	*	*	*

2. If the investment cost, schedule, or performance variances are not within 10 percent of the current baseline, provide a complete analysis of the reasons for the variances, the corrective actions to be taken, and the most likely estimate at completion.

3. For mixed lifecycle or operations and maintenance investments an Operational Analysis must be performed annually. Operational analysis may identify the need to redesign or modify an asset by identifying previously undetected faults in design, construction, or installation/integration, highlighting whether actual operation and maintenance costs vary significantly from budgeted costs, or documenting that the asset is failing to meet program requirements. The details of the analysis must be available to OMB upon request. Insert the date of the most recent or planned operational analysis.

4. Did the Operational analysis cover all 4 areas of analysis: Customer Results, Strategic and Business Results, Financial Performance, and Innovation?

Section C: Financial Management Systems

Table II.C.1: Financial Management Systems			
System(s) Name	System acronym	Type of Financial System	BY Funding
*	*	*	*

Section D: Multi-Agency Collaboration Oversight (For Multi-Agency Collaborations only)

Table II.D.1. Customer Table:	
Customer Agency	Joint exhibit approval date
NONE	

Table II.D.2. Shared Service Providers		
Shared Service Provider (Agency)	Shared Service Asset Title	Shared Service Provider Exhibit 53 UPI (BY 2011)
*	*	*

Table II.D.3. For IT Investments, Partner Funding Strategies (\$millions):							
Partner Agency	Partner exhibit 53 UPI (BY 2012)	CY Monetary Contribution	CY “In-Kind” Contribution	CY Fee-for-Service	BY Monetary Contribution	BY “In-Kind” Contribution	BY Fee-for-Service
NONE							

Table II.D.4. Legacy Systems Being Replaced		
Name of the Legacy Investment of Systems	Current UPI	Date of the System Retirement
*	*	*

Section E: Performance Information

Table I.E.1a. Performance Metric Attributes

Measurement Area (For IT Assets)	Measurement Grouping (For IT Assets)	Measurement Indicator	Reporting Frequency	Unit of Measure	Performance Measure Direction	Baseline	Year Baseline Established for this measure (Origination Date)
Technology	External Data Sharing	# of Center Registration Systems Accessed via Center Views. Outcome: Greater efficiency of import reviewers due to faster information sharing	quarterly	Number of Center registration systems	Increase	0 systems	2006-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2007	4 systems	Success. 4 Center systems accessed via web through Center Views	Met	2011-02-28
			2008	6 systems	Success. Center Views accesses 8 Center systems.	Met	2011-02-28
Mission and Business Results	Workforce Planning	# of districts that have automated support for assignment & scheduling. Outcome: Improved management of worker resources	annual	Number of districts	Increase	0 districts	2005-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2006	19 districts	Success. 19 districts. Completed	Met	2011-02-28
Processes and Activities	Risk	# of import product types screened based on calculated risk factors. Outcome: Higher may proceed rate for low risk products, more	annual	Number of food import product types	Increase	0 food product types	2005-10-15

resources for higher risk
food products

Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2006	development of pilot for screening	Success. Completed	Met	2011-02-28
2007	1 food product type	Success. 1 Product Type (Seafood) tested	Met	2011-02-28
2008	3 food product types	Failure. PREDICT Pilot supports 1 food product type.	Not Met	2011-02-28
2009	80% of food product types	Success. 100% of food product types	Met	2011-02-28

Processes and Activities	Efficiency	# of imported products screened per year within a window of two hours. Outcome: Meeting the two hour time window available for screening from Customs and Border Patrol operations as required by law. Reduced impact on commerce (cost to industry)	annual	Number of imported products	Increase	14,000,000 imported products	2006-10-15
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Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2007	15,000,000 imported products	Success. 15,000,000 imported products	Met	2011-02-28
2008	16,000,000 imported products	Success. More than 16,000,000 imported products.	Met	2011-02-28
2009	17,000,000 imported product lines	Success. 17,000,000 imported products	Met	2011-02-28
2010	18,000,000 imported product lines. Supports FY2011 CJ PM 214202, 214203, 214204	Success. 18,000,000 imported product lines	Met	2011-02-28

			2011	19,000,000 imported product lines. Supports FY2011 CJ PM 214202, 214203, 214204	TBD		2010-09-15
			2012	20,000,000 imported products	TBD		2010-09-15
			2013	21,000,000 imported product lines	TBD		2010-09-15
			2014	22,000,000 imported product lines	TBD		2010-09-15
			annual	Number of sources	Increase	0 sources	2007-10-15
Mission and Business Results	Border and Transportation Security	# of sources automatically mined for bioterrorism food processing. Outcome: Lower risk of imminent threats due to food					
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	1 source	Success. PREDICT Pilot automatically mines 1 source.	Met	2011-02-28
			2009	2 sources	Success. 2 sources	Met	2011-02-28
			2010	3 sources. Supports FY2011 CJ PM 214202, 214203, 214204	Success. 3 sources automatically mined	Met	2011-02-28
Mission and Business Results	Population Health Management and Consumer Safety	# of states that have access to an automated checklist for BSE threat analysis. Outcome: Enables the states to conduct effective BSE inspections	annual	Number of states	Increase	0 states	2006-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2007	50 states	Success. 50 states	Met	2011-02-28

Technology	IT Contribution to Process, Customer, or Mission	# of work functions available on mobile devices. Outcome: Decreased amount of time needed to perform inspections, investigations, exams, and collections	annual	Number of work functions	Increase	2 work functions	2007-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	3 work functions	Success. Establishment Inspection Report, 483 (adverse observations), and International Mail Facility	Met	2011-02-28
Customer Results	Customer Complaints	% comments are complaints about screens. Outcome: Increased user satisfaction and productivity.	annual	% comments	Decrease	65% of comments are complaints	2007-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	60% of comments are complaints	Success. Complaints reduced to less than 60%.	Met	2011-02-28
			2009	55% of comments are complaints	Success. 54% of comments are complaints	Met	2011-02-28
			2010	50% of comments are complaints	Success. 50% of comments are complaints	Met	2011-02-28
Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Certification, Third Party, and Audit functionality deployed resulting in greater effectiveness in leveraging other organizations. This is an improvement in work flow over the legacy	annual	Percentage of Certification, Third Party, and Audit functionality	Increase	0% deployment and rollout	2009-10-15

systems.

			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2014	100% deployment and rollout	TBD		2010-09-15
Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Compliance and Compliance Follow Up functionality deployed resulting in greater effectiveness in conducting compliance activities. This is an improvement in work flow over the legacy systems.	annual	Percentage of Compliance and Compliance Follow Up functionality	Increase	0% deployment and rollout	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2014	100% deployment and rollout	TBD		2010-09-15
Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Field Exam functionality deployed resulting in greater effectiveness in conducting field exams. This is an improvement in work flow over the legacy systems.	annual	Percentage of Field Exam functionality	Increase	0% deployment and rollout	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	100% deployment and rollout	TBD		2010-09-15
Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Inspection functionality deployed resulting in	annual	Percentage of Inspection functionality	Increase	0% deployment and rollout	2009-10-15

		greater effectiveness in conducting inspections. This is an improvement in work flow over the legacy systems.					
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	100% deployment and rollout	TBD		2010-09-15
Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Investigation functionality deployed resulting in greater effectiveness in conducting investigations. This is an improvement in work flow over the legacy systems.	annual	Percentage of Investigation functionality	Increase	0% deployment and rollout	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2013	100% deployment and rollout	TBD		2010-09-15
Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Recall Audit Check functionality resulting in improved recall capability and leverage of State resources	annual	Percentage of Recall Audit Check functionality	Increase	0% deployment and rollout	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2011	100% deployment and rollout. Supports FY2011 CJ PM 214205, 244202, 224201	TBD		2010-09-15
Mission and Business Results	Population Health Management and	% deployment and rollout of MARCS	annual	Percentage of Sample Analysis functionality	Increase	0% deployment and rollout	2009-10-15

Consumer Safety

Sample Analysis functionality deployed resulting in greater effectiveness in conducting Sample Analyses. This improves the ORA laboratory capability. This is an improvement in work flow over the legacy systems.

Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2013	100% deployment and rollout	TBD		2010-09-15

Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of MARCS Sample Collection functionality deployed resulting in greater effectiveness in conducting sample collections and for preparing data for sample analysis. This is an improvement in work flow over the legacy systems.	annual	Percentage of Sample Collection functionality	Increase	0% deployment and rollout	2009-10-15
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Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2013	100% deployment and rollout	TBD		2010-09-15

Mission and Business Results	Population Health Management and Consumer Safety	% deployment and rollout of remaining MARCS Recall functionality deployed resulting in greater effectiveness in conducting recalls. This is an improvement in work flow over the legacy systems.	annual	Percentage of remaining Recall functionality	Increase	0% deployment and rollout	2009-10-15
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			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2013	100% deployment and rollout	TBD		2010-09-15
Technology	Internal Data Sharing	% disparate functionality harmonized between legacy systems. Outcome: Greater efficiency for investigators, analysts, and compliance officers	annual	% of functionality	Increase	0% of functionality	2007-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	20% of functionality	Success. Single Sign On and Firm Finder (20% of functionality).	Met	2011-02-28
			2009	36% of functionality	Success. 36% of functionality	Met	2011-02-28
Mission and Business Results	Criminal Investigation and Surveillance	% of compliance actions share automated workflow actions and evidence captured with Centers. Outcome: Increased efficiency and speed in producing successful performance cases	annual	Percentage of compliance actions	Increase	0% of compliance actions	2007-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	20% of compliance actions	Success. Data pulled from Domestics into Case Management System (20% of compliance actions).	Met	2011-02-28
			2009	30% of compliance actions	Success. 30% of compliance actions	Met	2011-02-28
			2010	40% of compliance actions	Success. 42% of compliance actions	Met	2011-02-28

Processes and Activities	Risk	% of import product types screened based on calculated risk factors. Outcome: Higher may proceed rate for low risk products, more resources for higher risk device products	annual	Percentage of device product types	Increase	0% of device product types	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2011	80% of device product types. Supports FY2011 CJ PM 253201, 254201	TBD		2010-09-15
Processes and Activities	Risk	% of import product types screened based on calculated risk factors. Outcome: Higher may proceed rate for low risk products, more resources for higher risk drug products	annual	Percentage of drug product types	Increase	0% of drug product types	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2010	80% of drug product types	Success. 80% of drug import product types	Met	2011-02-28
Technology	Standards Compliance and Deviations	% of Infrastructure 24/7 compliant that is required to be 24/7 Compliant. Outcome: Compliance with Bioterrorism Act to check every food product and conformation to Customs and Border Patrol's two hour time window	annual	Percentage of infrastructure	Increase	0% of infrastructure	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated

			2010	100% of infrastructure. Supports FY2011 Congressional Justification (CJ) Performance Measure (PM) 214201	Success. 100% of infrastructure 24/7 compliant that is required to be 24/7	Met	2011-02-28
Technology	Standards Compliance and Deviations	% of Infrastructure brought to Current Standard (VMS to Unix). Outcome: Reliable infrastructure supporting key agency missions	annual	Percentage of infrastructure	Increase	20% of infrastructure	2007-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	80% of infrastructure	Success. UNIX I implemented. All major systems and databases (80% of infrastructure) now at current standard.	Met	2011-02-28
			2009	100% of infrastructure	Success. 100% of infrastructure	Met	2011-02-28
Technology	Standards Compliance and Deviations	% of Infrastructure brought to Current Standard (Web from C/S). Outcome: Improved application maintainability and reduced cost	annual	Percentage of infrastructure	Increase	0% of infrastructure	2005-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2006	100% of infrastructure	Success. 100% of existing legacy converted from C/S to Web	Met	2011-02-28
Technology	External Data Sharing	% of Interfaces with Center Databases standardized. Outcome: Greater workflow efficiency and more effective decision making resulting in	annual	Percentage of interfaces with Center databases	Increase	20% of interfaces	2006-10-15

stronger enforcement
cases

Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2007	70% of interfaces	Failure. Goal not met. Work delayed.	Not Met	2011-02-28
2009	20% of interfaces	Success. 20% of interfaces	Met	2011-02-28
2010	70% of interfaces	Success. 70% of interfaces with Center databases standardized	Met	2011-02-28

Technology	Interoperability	% of MARCS functionality re-engineered from legacy systems into new components	annual	Percentage of functionality	Increase	5% of functionality	2009-10-15
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Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2011	15% of functionality	TBD		2010-09-15
2012	40% of functionality	TBD		2010-09-15
2013	90% of functionality	TBD		2010-09-15
2014	100% of functionality	TBD		2010-09-15

Customer Results	Frequency and Depth	% of work flows designed for handheld use available on handhelds.	annual	Percentage of work flows	Increase	0% of work flows available on handhelds	2009-10-15
			Fiscal Year	Target	Actual Results	Target “Met” or “Not Met”	Last Updated
			2013	25% of work flows available on handhelds	TBD		2010-09-15

Customer Results	Frequency and Depth	% of work flows designed for offline use available offline.	2014	100% of work flows available on handhelds	TBD		2010-09-15
			annual	Percentage of work flows	Increase	5% of work flows available offline	2009-10-15
Technology	IT Contribution to Process, Customer, or Mission	% of work flows handled via a Business Process Management Suite supported by an Enterprise Service Bus on a Service Oriented architecture	Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2011	15% of work flows available offline. Supports FY2011 CJ PM 214205, 244202, 244203, 224201, 234202, 234203, 244202, 253201, 254201	TBD		2010-09-15
			2012	50% of work flows available offline	TBD		2010-09-15
			2013	90% of work flows available offline	TBD		2010-09-15
			2014	100% of work flows available offline	TBD		2010-09-15
			annual	Percentage of work flows	Increase	0% of work flows	2009-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2011	15% of work flows. Supports FY2011 CJ PM 214201, 214202, 214203, 214204, 214205, 244202, 244203, 224201, 234202, 234203, 244202, 253201, 254201	TBD		2010-09-15
			2012	40% of work flows	TBD		2010-09-15

			2013	90% of work flows	TBD		2010-09-15
			2014	100% of work flows	TBD		2010-09-15
Mission and Business Results	Workforce Planning	% of Workforce Planning/scheduling functions in current stovepipes integrated. Outcome: Decreased cost of assigning staff to inspections	annual	Percentage of workforce planning and scheduling functions	Increase	20% of workforce functions	2007-10-15
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2008	25% of workforce functions	Success. National Sample Distributor implemented (25% of workforce functions).	Met	2011-02-28
			2009	30% of workforce functions	Success. 30% of workforce functions	Met	2011-02-28
			annual	Percentage reduction in complaints	Decrease	Ongoing complaints	2005-10-15
Customer Results	Customer Complaints	% Reduction in Complaints about printing capabilities in the field. Outcome: Increased customer satisfaction and productivity for field employees	Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2006	100% reduction	Success. 100% --Release of enhancements packaged with Web Version of FACTS/OASIS eliminated all print complaints	Met	2011-02-28

* - Indicates data is redacted.